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APPEAL BRIEF: Official Copy for the Appeals Board

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/604469

Applicant: Iftikhar Khan et al.

Group Art Unit: 3763

Examiner: Theodore Stigell

Title: Orotracheal Suction System

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Commissioner for Patents

P.O. Box 1450

Application No: 10/604469 Official Copy

Alexandria, Virginia 22313-1450

Sir:

As follows are remarks to the board of Appeals

AMENDMENTS TO THE CLAIMS

The following listing of claims will replace all prior versions and listings of claims in the application.

LISTING OF CLAIMS

1-9. (Cancelled)

10. (Previously Amended) An orotracheal suction system for suctioning obstructive material from the oropharynx and trachea of a patient, the system comprising: a catheter having a distal end and a proximal end, a diameter of from about 0.5 Fr to about 15 Fr, and a length sufficient to engage the oropharynx and distal bronchi of the patient at the catheter distal end; a seal at the distal end of the catheter;an extension tubing operable for attachment to the catheter proximal end and extending a distance away from the

patient's head and mouth; and a reservoir operable to connect to the extension tubing and to collect the obstructive materials using a vacuum source; wherein the reservoir comprises an entry compartment and a second compartment, wherein the compartments are separated by a grid operable to prevent obstruction of the vacuum by the obstructive material.

11. (Cancelled)

12. (Cancelled)

13. (Previously Presented) The orotracheal suction system of Claim 10, wherein the reservoir comprises a removable disc to empty the obstructive material from the reservoir.

14. (Previously Presented) The orotracheal suction system of Claim 10, wherein the catheter and extension tubing have a diameter to accommodate an obstructive food bolus.

15. (Cancelled)

16. (Previously Presented) The orotracheal suction system of Claim 10, wherein the seal comprises a balloon and wherein the catheter further comprises a balloon port to inflate the balloon.

17. (Previously Presented) The orotracheal suction system of Claim 10, wherein the extension tubing has a length of from about 3 feet to about 5 feet.

18. (Withdrawn) A method of removing an obstructive material from the oropharynx and trachea of a patient comprising: providing catheter having a distal end and a proximal end, and a length sufficient to engage the oropharynx and distal bronchi of the patient at the catheter distal end;

a seal comprising a balloon at the distal end of the catheter; and a reservoir having an entry chamber operable for connection to the

catheter to collect the obstructive materials using a vacuum source;

disposing the distal end of the catheter into the oropharynx;

sealing the trachea by inflating the balloon at the distal end of the catheter;

drawing vacuum pressure through the reservoir and proximal end of the catheter

to suction the oropharynx to remove the obstructive material; and

trapping the obstruction in the entry chamber of the reservoir.

19. (Withdrawn) The method of Claim 18, wherein the obstructive material is a foreign body, a mucous plug, or a food bolus.

20. (Withdrawn) The method of Claim 18, further comprising disposing the catheter distal end in the trachea above the distal bronchi.

21. (Withdrawn) The method of Claim 20, further comprising suctioning the bronchi.

22. (Withdrawn) The method of Claim 18, wherein the catheter further comprises a balloon port, and inflating the balloon comprises engaging the balloon port.

23. (Withdrawn) The method of Claim 18, wherein the catheter is connected to the entry chamber of the reservoir through an extension tubing

attached to the proximal end of the catheter.

24. (Withdrawn) A method of removing an obstructive material from an oropharynx and trachea of a patient comprising: providing a catheter having a distal end and a proximal end, a diameter sufficient to accommodate a food bolus, and a length sufficient to engage the oropharynx and distal bronchi of the patient at the catheter distal end; a seal comprising a balloon at the distal end of the catheter; an extension tubing having a first and second end, operable for attachment to the catheter proximal end and extending a distance away from the patient's head and mouth; and

a reservoir having an entry chamber with a first connection and a second chamber with a second connection, the entry and second chambers being separated by a grid operable to keep large particles in the entry chamber; and disposing the distal end of the catheter into the trachea and above the distal bronchi; attaching the proximal end of the catheter to the first end of the extension tubing; connecting the second end of the extension tubing to the first connection on the reservoir; connecting a wall vacuum source to the second connection on the reservoir: sealing the trachea by inflating the balloon at a distal end of the catheter; drawing vacuum from the wall vacuum suction through the reservoir, extension tubing and catheter so as to suction the oropharynx and trachea to remove the food bolus; and trapping the food bolus in the entry

chamber of the reservoir.

25. (Withdrawn) The method of Claim 24, wherein the catheter has a diameter of from about 0.5 Fr to about 15Fr.

26. (Withdrawn) The method of Claim 25, wherein the catheter has a diameter of from about 8 Fr to about 15 Fr.

27. (Withdrawn) The method of Claim 24, wherein the extension tubing extends from about 3 feet to about 5 feet away from the mouth of the patient.

28. (Withdrawn) The method of Claim 24, wherein the extension tubing has a diameter of from about 0.5 Fr to about 15Fr.

29. (Withdrawn) The method of Claim 28, wherein the extension tubing has a diameter of from about 8 Fr to about 15 Fr.

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REMARKS

Let us look carefully at the basis of the claims rejections to see why there is no basis for any of the rejections. The quotation of 35 U.S.C. 103(a) "which form the basis for all obviousness rejections set forth in the office action" as the examiner states. It relies exclusively on the fact that the examiner can comprehend what ordinary skill in the art he or she is examining is. From viewing all the communications these examiners have written it is clear that they do not know what ordinary skill in this art is and will not. A person with ordinary skill in this art is someone who is allowed to actually use such a devices to perform the life saving procedures at critical times when a patient needs it. It requires that the person with this ordinary skill has dissected the structures and on a human body and studied the organs and vascular and pulmonary structures to the highest degree as taught in United States medical schools. It would require that person with such "ordinary skill" to excel in medical school to be selected for training which few of the graduates can attain. It would require that person be allowed to perform these procedures on live patients, where one is attempting to access the pulmonary system in an emergent manner to relieve acute airway obstruction. This would require to person of "ordinary skill" to be selected for emergency medicine or thoracic surgery training. It would require this person of "ordinary skill" to perform at a high level for 110-130 hrs/wk to be allowed the privilege to handle these devices at critical times to save patients lives. To still perform these tasks in the middle of the night, even though you have been awake for 40hrs. There is no substitute for actually having the experience, skill and medical knowledge which comes from over

10 years of the most intensive medical training a person can experience. Ted Stigell cannot learn these things by simply reading about what other people's patents are on paper. The examiner cannot hyperspace into this position and give an opinion on what "ordinary skill" in this art when he has absolutely no comprehension of what that person's knowledge and skill level is. It is impossible.

It negates the basis for all of his rejections because in no way can understand what ordinary skill in this art even is, at his current level of education and training. One cannot go from zero medical training to understanding the limitations, functions and nuances of medical devices and procedures that it takes some with "ordinary skill" in the art 10 years of intensive medical training to achieve. I asked the examiner to present his training and education and reasons he would know what "ordinary skill in the art" of emergency medicine and thoracic surgery, and specifically relieving acute airway obstruction with seriously invasive instrumentation in the last communication, but he did not and cannot.

If need be, based on the result of this appeal, I am very willing to take matter the matter to federal court where the examiners can state explicitly how they achieved understanding of "ordinary skill" in this art to render an opinion on what a person with "ordinary skill" would be able to develop based on their cited previous art. I will also try this matter, in civil court, to reclaim lost time and wages regarding dealing with the examiners in this case.

I cannot render opinions on what ordinary skill in the art of designing new O rings on the space shuttle. I have no training or education in

aerospace engineering. It would ridiculous. These examiners have no graduate medical training or even basic anatomical training one would receive in medical school. They cannot render any opinion on what ordinary skill in this art is until they achieve that level of knowledge and procedural skill with regarding these devices which comes as mentioned with over 10 years of medical and surgical training and education.

I will now respond to the examiners specific rejections. The statement made by the examiner in his last final rejection of 2/12/08 stating "it is clear that the system would work just as well with a standard suction canister as it would with the claimed reservoir. How exactly does Mr. Stigell know that? Has he used different suction systems before? (No) Has he connected the tubing and seen what the diameter is and flow rate that standard that a standard container can achieve ?(No). Has he seen suction tubing obstruct when trying to remove foreign material over the glottis of a patient (No). Where is the glottis , Mr. Stigell? One with ordinary skill in the art or someone rendering an opinion about persons with ordinary skill. which Mr. Stigell is doing, would know this and he sadly does not.

My previous patent attorney presented that the system can be used with a standard container. It is feasible, but not preferable. I can state here for the record that it is not preferable to use my suction system with a standard canister because the debris may obstruct the inlet and outlet source to the vacuum. It is preferable to use the suction system.

In response to the assertion by the examiner that "the structure defined in claim 10 can be used in a materially different process such as suctioning the mouth or a wound in the body." No Sir, it cannot. The said structure defined in claim 10 is beveled at the tip and cannot be used for "a wound on the body". It is clear the examiner because of his profound lack of medical knowledge does not know what is a "wound on the body. The examiner did not define a wound on the body. One who was rendering opinions about ordinary skill in this art would know that many "wounds on the body" have small delicate structures; nerves, tendons, micro-arterial and venous structures and connective tissues which would be destroyed by our orotracheal suction to be applied to them. A suction intended for use in the oropharynx and trachea cannot be applied to any "wound on the body." If Mr. Stigell understood what ordinary skill in the art this comparison would not be made. Suctioning a surgical or traumatic wound on the body, given

the size and the particular structures involved, is a completely different enterprise requiring specific suctioning catheters and equipment which are protected by different patents even though they are providing an apparatus which suctions. It depends on where the wound is, what has been injured, how deep the wound is and what are the particular fine structures involved-none of which Mr. Stigell takes into account because he has no knowledge or training in this art.

There are multiple inventions which are inherently the same device, but used for very different applications even though they have the same basic structure. A Foley catheter is basically a catheter with a balloon. A Swanz-Ganz is basically a catheter with a balloon. A Fogarty catheter is basically

another catheter with a balloon which is used to remove arterial and venous obstruction. The Foley is used to drain the bladder. A Swan-Ganz is used to measure pulmonary capillary wedge pressure, as well as left ventricular end diastolic pressure and cardiac output. One with ordinary skill in the art could easily come up with the Swan Ganz and the Fogarty Catheter since they are essentially the same structure and device as the Foley: flexible catheters with balloons at the distal ends. The Swan-Ganz catheter and Fogarty are even used in the same organ system- the arteriovenous system; I am willing to accept that my invention is not patentable under 35 U.S.C. 103(a) if the examiner can invalidate the patents of the Swanz-Ganz and Fogarty catheters which are **essentially the same devices,** yet they have received patent protection. How more obvious and similar can these devices be, yet somehow they achieved patent protection. It defies reason that Ted Stigell can render opinions about what individuals with "ordinary skill" in this art could develop, when he has no training or skill in this art, yet these catheters with balloons have been awarded patents but they are essentially the same device. Mr. Stigell did not have any answer to this in the previous communication.

In this case, the examiner has rejected claims 10.13,14 16-17 as unpatenable over

Pell(U.S. Pat. No.4,850,348). et al, in review of Wood (GB)2,220,357 and Joseph (US Pat no 5819723)

He has cited three patents that are unrelated to each other and to the applicant's device. Pell's device as mentioned before has no function to suction the

oropharynx or trachea and as previously presented has no design to capture debris into a receptacle. It is a tube used for endotracheal intubation for use with a ventilator and as a positioning device in the mouth. It has no structure or mechanical design to allow for any suction

Someone with "ordinary skill" in the art cannot think of using this device for any other purpose or they would have seriously less than even ordinary skill, or better stated no skill or dangerous skill in the art. The examiner cannot comprehend this because he has zero skill or knowledge in the art and cannot possibly make determinations of what a person with ordinary skill in the art would be able to fashion based on the devices of Pell, Jospeh and Wood. Pell again does not disclose any of the limitations I have disclosed. Mr. Stigell makes blanket statements such as "Pell discloses most of the limitations recited by the applicant." How exactly does Pell do this? His device is for endotracheal intubation and ventilation. It is not intended for or have limitations which extend to a suction system to remove particulate foreign debris Mr. Stigell does not understand these devices or has he ever personally used such devices. There is only so much you can garner from reading other peoples ideas and looking for similarities. I could then invalidate every vascular surgical device because it resembles a garden hose and they both carry fluid using the examiner's logic. In light of the fact that the devices I have mentioned (Fogarty, Swan-Ganz, and Foley catheter) are essentially the same device and even used in the same organ system. his reasoning is very flawed. I cannot take Mr. Stigell through 10 years of medical and surgical training to understand these devices, how they are used, and their exact limitations. Therefore

claims 10, 13-14, and 16-17 are not to be rejected under 35 U.S.C.

I know from his description of these devices that Mr. Stigell does not know what the devices he is citing actually do and therefore cannot understand their limitations. He does not understand if Pell's device can even be employed with assist control or SIMV ventilation or what happens when foreign material will obstruct the lumen of Pell's device. He certainly cannot comprehend what someone with ordinary skill in the art could develop up in light of Pell's device.

He writes that Wood discloses "a suction catheter system that is designed to remove blood, irrigation liquid" during a surgical procedure. Mr. Stigell does not understand any of the limitations of this device. One with ordinary skill in this art would understand that you cannot take a marginal wound-vacuum suction which is what Wood's device is and somehow conceive of my device in light of Pell's device or Joseph's invention. The structures a wound suction contacts are particular and delicate as mentioned above and they include the fine vascular and neural structures that a fractions of a millimeter in diameter. It also depends on the size of the wound. Its uses, design and limitations are not for the oropharynx, supraglottic and subglottic spaces or the tracheal or distal bronchial structures. It is like looking at a shop-vac in your garage and using it to invalidate the patent protection of all suctions that have specific medical uses in particular areas of the human anatomy. That is how related Woods device is to my device and to the other devices. Again as stated, Mr. Stigell does not have the knowledge or technical skill in this art to render and opinion on what someone with ordinary skill in this art

would be able to construct in light of three unrelated devices he has cited so his rejections are not valid and should be withdrawn.

The device from Joseph as I mentioned ad nauseum previously to examiner Stigell, functions to remove a few if that milliliters of tracheal secretions to improve tracheal hygiene in intubated patients. It is designed to irrigate the area of the proximal trachea only to remove excessive accumulation of fluid in the proximal trachea only. It has no designed apparatus to allow for suctioning and more importantly it is not designed for any removal of debris from the distal trachea or the oropharynx. Someone with ordinary skill cannot in any conceivable way look at the this device "in light" of Pell and Wood and somehow clearly develop a functional device to clear the oropharynx, proximal trachea, distal trachea, proximal bronchi and distal bronchi. The arguments and time wasted with Examiner Stigell were endless. Questions I could have answered all at once and saved considerable time, were sent in piece-mail to extend this process, all the time incurring attorney fees. Every time, I had to discuss the basics of these devices in my communications, because he does not understand them, nor has he every seen them actually in practice. How could he given a lack of basic understanding of "ordinary skill" in this art.

I present for the appeals board why I have ordinary skill in this art. I graduated at the top of my medical school class from a United States medical school. I was selected to the medical honor society. I scored a 99% on my US medical licensing exam, one of the most difficult professional licensing exams in the world. I served as the chief of my residency. I was selected to surgical and

emergency medicine training programs at two of the top hospitals in our nation. I practice this art every day of my life. I have studied this art at the highest level through 10 yrs of graduate medical training and now practical experience as an attending physician in some of the top hospitals in the world.

I can estimate what ordinary skill in this art as well as extraordinary skill. What did I know about ordinary skill in this art after obtaining an undergraduate degree in biology(nothing). What did I know about ordinary skill in this art after obtaining a Doctor of Medicine degree? (at least something, but not ordinary skill) I covered the physiology and anatomy of the human body with rigorous detail and was able to assist physicians in implanting these devices in live patients in the operating room. What did I know about ordinary skill in this art after training for 6 years in the intensive care unit, emergency department, and operating room actually handling and using the devices to save critically ill patients? (ordinary skill in the art). What do I know now that I am board certified by the American Board of Emergency Medicine and now selected as a fellow of the American College of Emergency Physicians (more than ordinary skill in the art). It is a difficult, highly selective process that takes 13 yrs after starting medical school. Mr. Stigell cannot conjecture about what ordinary skill in this art is and what a person with ordinary skill in the art might be able to develop or not, when he himself has zero skill, knowledge or actual training in this art. I welcome him to try to start the process. The basis for all of his rejections is therefore invalid and the rejections should be all removed. It has all been a house of cards- I wish I had recognized it earlier.

I am very serious about this next point. I will try the matter in federal court, and Mr. Stigell can discuss how exactly he has ordinary skill in the art. I will also recover immense lost time and wages in civil court against these examiners and for what has been stated above and the reasons below.

My patent attorney and many others have said, the goal is for the examiner to prolong this as long as possible, almost always issuing a final rejections and charging more fees. This process is determined to exhaust the individual inventor until they just give up or are bankrupt. I never give up.

The examiner ,Ted Stigell, also sent me a duplicate request for changes to the drawings after I had sent him the changes 3 months prior. The process is already frustrating and this lack of competence makes it more so. Lest he forget, I documented in an email to him which is saved and to Frederick Schmidt, the director of the entire unit and my attorneys. I called Nick Luchesi, but he does not respond to any phone calls, ever, which has been mentioned to Director Schmidt. Again, no mention of this point in the last communication. This device could save many citizens here and soldiers abroad dying needlessly from acute aspiration and lung injury caused by airway obstruction. I developed my device when a patient before was dying from acute airway obstruction and there was no device available to quickly remove the obstruction. I thankfully was at a large tertiary care hospital, which is one of the best staffed and equipped on earth, so we were able to take the patient to surgery and relieve the obstruction. Very few hospitals have this capability and I want them to have it because it may be you at one of these small hospitals dying from acute airway obstruction and I would like

this equipment available to help these providers that do not always have the support and training to deliver this service.

The following states the remarks for traversal of the rejections which were drafted and specifically counter Mr. Stigell rejections and are valid given there is no basis for his rejections. They are included for review. Claims 10, 13, 14, and 16-29 are now pending in the application. Claims 18-29 have been withdrawn from consideration. Claims 11, 12, and 15 have been cancelled and the subject matter has been incorporated into Claim 10. Claim 10 as amended now recites that the reservoir includes an entry compartment and a second compartment, that the compartments are separated by a grid, and that the catheter has a diameter of from about 0.5 Fr to about 15 Fr. No new matter has been added. The Board of Appeals is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

RESTRICTION UNDER 37 C.F.R. 1.142(B)

Applicant respectfully traverses the restriction under 37 C.F.R. 1.142(b) whereby the Examiner withdrew Claims 18-29 from consideration. Claims18-29 have a sufficient connection to Claims 10-17 such that the restriction is improper. Claims 18-29 are connected to Claim 1 by at least one of

the design of the orotracheal suction system, the operation of the orotracheal suction system, and the effect of use of use of the orotracheal suction system. MPEP §802.01(11). Specifically, Claim 18 incorporates the design of the orotracheal suction system of Claim 1, and in turn the system of Claim 1 is required for operation of the method of Claim 18. Further, there is no additional burden placed on the board by considering the related claims together because the apparatus and methods are so related that no extraneous searching or analysis would be required. Accordingly, Applicant asserts that the restriction is improper and requests that Claims 18-29 be considered with Claims 10-17.

REJECTION UNDER 35 U.S.C. § 102

Claims 10, 14, and 16 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Pell et al. (U.S. Pat. No(4,850,348). This rejection is respectfully traversed. Pell et al. disclose an endotracheal apparatus made of a material that bends through substantially 90 degrees without the wall collapsing or kinking due to a special tube material formed of silicone, a silica filler, and platinum salts. Column 2, line 62 through Column 3, line 11. The Pell et al. apparatus is disclosed as being adapted to be connected to a ventilator or oxygen source and/or a suction device. Column 3, lines 40-43 and Column 5, lines 27-33.

The focus of the Pell et al. disclosure is the bendable and non-collapsible material, and Pell et al. provide no disclosure on the specifics of the reservoir being formed as a multi-compartment chamber having a grid

separating the entry and second compartments. The Office Action asserts, however, that Pell et al. disclose "a reservoir (the suction source, column 5, line 33) operable to connect to the extension tubing... wherein the reservoir comprises an entry compartment and a second compartment as all reservoirs do..." Office Action at page 5. Applicant is unsure of the foundation of the Office's assertion that "the reservoir comprises an entry compartment and a second compartment as all reservoirs do." Office Action at page 5, emphasis added. As Pell et al. do not disclose any details for the reservoir or for the separating grid, Pell et al. do not disclose each and every element of Applicant's claimed invention as amended, and the §102 rejection is improper. Reconsideration and removal of the §102 rejection of the claims are respectfully requested.

Claims 10, 13-14, and 16-17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Joseph (U.S. Pat. No. 5,819,723). This rejection is respectfully traversed. Joseph discloses a tracheal tube system and related methods for preventing the spread of infected secretions into the distal trachea where the tracheal tube system blocks the infected secretions and delivers an irrigating liquid to the area via an irrigation channel near the exterior surface of the tracheal tube. Column 4, lines 34-53 and Column 7, lines 46-62. Joseph discloses a canister 402 for removing aspirated fluids and a suction regulator, where the suction source is typically wall suction. Column 8, lines 13-28.

Joseph does not disclose any additional information on the canister 402 and provides no

disclosure on the specifics of the reservoir being formed as a multi-compartment chamber having a grid separating the entry and second compartments.

The Office Action indicates that Joseph discloses "a reservoir (402) operable to connect to the extension tubing... wherein the reservoir comprises an entry compartment and a second compartment as all reservoirs do, wherein the reservoir has a grid and a removable disc..." Office Action at pages 5-6. Again, Applicant is unsure of the foundation of the Office's assertion that "the reservoir comprises an entry compartment and a second compartment as all reservoirs do." Office Action at page 5, emphasis added. As Joseph does not disclose any details for the reservoir, Joseph does not disclose each and every element of Applicant's claimed invention as amended, and the §102 rejection is improper. Reconsideration and removal of the §102 rejection of the claims is respectfully requested.

CONCLUSION

Applicant submits that a full and complete response has been made to the outstanding to the final rejection and the present application is in condition for allowance. I thank the appeals board.

Iftikhar Khan MD, Fellow of the American College of Emergency Physicians